UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,993	11/04/2003	Charles R. Saikley	ADC-510	6633

73719 7590 01/14/2009

SF Bay Area Patents, LLC
Attn: Andrew V. Smith, Ph.D.
601 Van Ness Avenue, #1108
San Francisco, CA 94102

EXAMINER	
HOEKSTRA, JEFFREY GERBEN	
ART UNIT	**PAPER NUMBER**
3736	

MAIL DATE	DELIVERY MODE
01/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/701,993	SAIKLEY ET AL.	
	Examiner	Art Unit	
	JEFFREY G. HOEKSTRA	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-57* is/are pending in the application.

4a) Of the above claim(s) *36-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-35 and 52-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice of Amendment

1. In response to the amendments filed on 10/20/2008, amended claim(s) 21 is/are acknowledged. The current rejections of the claim(s) 21-35 and 52-56 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 21-35 and 52-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham et al. (US 6,306,104 B1, hereinafter Cunningham) in view of Moerman et al. (US 2003/0191415 A1, hereinafter Moerman).

4. For claims 21 and 23, Cunningham discloses a bodily fluid testing device (10, 900, 1000) for obtaining and testing a bodily fluid sample, the bodily fluid sample capable of being a submicroliter bodily fluid sample, comprising:

- a housing (12) defining a first aperture (33);
- a lancing device (16, 67, 908, 1016) including a lancet drive (60) including a spring (68), the lancing device:
    - operatively coupled to said housing by said spring (column 10 lines 1-31) (as best seen in Figures 21-22),
    - capable of obtaining a submicroliter bodily fluid sample by advancing through said first aperture,

- piercing a skin surface at a bodily fluid sample location (column 6 lines 17-30 and column 9 lines 29-57), and
- withdrawing to provide access to the submicroliter bodily fluid sample by a test strip (914, 1014); and

- a mount block (903, 1003) coupled with a connector that is coupled with a motor (column 32 line 55 – column 33 line 39) within the housing,
  - the mount block configured for coupling the test strip thereto (as best seen in Figures 13-14),
  - wherein the motor is capable of moving the mount block and an edge of the test strip along a trajectory such that a bodily fluid receiving portion (column 7 line 65 – column 8 line 36 and column 16 lines 40-56) of the edge of the test strip comes to rest at a center of the submicroliter bodily fluid sample without moving the housing relative to the bodily fluid sample location (column 32 line 55 – column 33 line 39) (as best seen in Figure 13E),
- wherein the bodily fluid testing device is configured such that the housing is placed on the bodily fluid sampling location, and then after said lancing and withdrawing of the lancing device, the edge of the test strip moves along the trajectory to the bodily fluid sample contacting location near the center of the bodily fluid sample in the plane of the skin surface at the bodily fluid sample location (as best seen in Figures 13C-13E).

5. For claim 22, Cunningham discloses the device of claim 21, wherein the lancing device comprises a cutting edge (the at least one lancet in column 6 lines 17-30 and

column 9 lines 29-57) that is aligned with the test strip, although withdrawn following lancing to provide said bodily fluid sample, when the test strip is received in the housing and moved to said center of the bodily fluid sample (as best seen in Figure 13E).

6. For claim 24, Cunningham discloses the device of claim 21, wherein the lancing device comprises a body having a first axis, and a sharp operatively connected to the body, wherein the sharp has a second axis that is substantially perpendicular to the first axis (column 6 lines 17-30 and column 9 lines 29-57).

7. For claim 25, Cunningham discloses the device, wherein the lancing device comprising a sharp with at least two points (column 6 lines 17-30 and column 9 lines 29-57).

8. For claim 26, Cunningham discloses the device, wherein the lancing device is of a construction sufficient to pierce tissue of a patient (column 6 lines 17-30 and column 9 lines 29-57).

9. For claims 27 and 52-56, Cunningham discloses the device, wherein the test strip comprises a side-filled test strip (as best seen in Figures 13B-13E) capable of sampling the submicroliter bodily fluid sample, wherein the submicroliter bodily fluid sample is capable of comprising a submicroliter volume, a volume of less than 1/3 of a microliter, and a diameter of not more than approximately 0.005 inches.

10. For claim 28, Cunningham discloses the device, wherein when the test strip is in the bodily fluid sample-contacting position, a fill channel (column 7 line 65 – column 8 line 36 and column 16 lines 40-56) of the test strip is capable of being aligned with the

submicroliter bodily fluid sample within 0.005 inches of said center of said sample (as best seen in Figure 13E).

11. For claims 29, 34, and 35, Cunningham discloses the device, wherein the edge of the test strip is capable of traveling along said trajectory including 0.03 inches along the bodily fluid sample location at an approach angle between 35 – 65 degrees.

12. For claim 30, Cunningham discloses the device, wherein the physiological property that is determined from the sample comprises a glucose level (Abstract).

13. For claim 31, Cunningham discloses the device, further comprising a controller (20) operatively coupled to the housing for controlling operation of the lancing device (column 13 lines 33-51).

14. For claim 32, Cunningham discloses the device, further comprising an input unit (1009) operatively coupled to the housing for operating the lancing device.

15. For claim 33, Cunningham discloses the device, further comprising a controller (20) operatively coupled to the housing for controlling movement of the test strip when the test strip is received in the housing (column 32 line 55 – column 33 line 39).

16. For claim 57, Cunningham discloses the device, wherein the device is capable of lancing without application of a vacuum to the bodily fluid sample location through the first aperture.

17. Thus for claims 21-35 and 52-57, Cunningham discloses the claimed bodily fluid testing device except for expressly disclosing the motor is configured to move the edge of the test strip along a nonlinear trajectory to the bodily fluid sample contacting location within a mechanical tolerance of 0.010 inch of the center of the bodily fluid sample in the

plane of the skin surface at the bodily fluid sample location and is configured to lance and test without application of a vacuum to the bodily fluid sample location through the first aperture.

18. Moerman teaches a bodily fluid testing device (10) (as best seen in Figures 1, 3, 6-9, and 28) (paragraphs 17, 35, 44-48, 114, 117-122, 124, 143-145, and 186-189), comprising *inter alia*: a motor (20 and 21) (paragraphs 124 and 143) configured to move an edge of a test strip (the edge of element 32a as best seen in Figure 28) (as best seen in Figures 1, 3, 6-9, and 28) (paragraphs 17, 35, 44-48, 114, 117-122, 124, 143-145, and 186-189) along a nonlinear trajectory (as best seen in Figure 28) to a bodily fluid sample contacting location (paragraphs 121 and 186-189) within a mechanical tolerance of 0.010 inch (paragraphs 121 and 186-189) in the plane of the skin surface at the bodily fluid sample location (as best seen in Figures 1, 3, 6-9, and 28) (paragraphs 17, 35, 44-48, 114, 117-122, 124, 143-145, and 186-189) and is configured to test without application of a vacuum to the bodily fluid sample location through a first aperture.

19. All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All of the component parts are known in Cunningham and Moerman. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the components as taught

by Cunningham with the components as taught by Moerman to achieve the predictable results of increasing the efficacy of a medical diagnostic device to operate with minimal bodily fluid sample by configuring the mechanical tolerance of a test strip trajectory with increased accuracy.

Response to Arguments

20. Applicant's arguments with respect to claims 21-35 and 52-57 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY G. HOEKSTRA whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey G Hoekstra/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736